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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,978	07/11/2003	Rafael Herrmann	035718/260673	4095

29122 7590 05/26/2006

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,978	HERRMANN ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006 and 10 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11-31 and 38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13-19,21-31,38,40,42 and 43* is/are rejected.

7)☒ Claim(s) *11,12,20,39 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7, 11-31 and 38-43 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The abstract is not descriptive of the instant invention, which is a nucleic acid encoding a pesticidal protein from Androctonus amoreuxi, plants comprising it, and a method of using it to increase plant pest resistance. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The objection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2005. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

Applicant urges that the abstract has been amended to recite compositions and methods for orally active Androctonus amoreuxi proteins (response pg 10).

This is not found persuasive because the instantly claimed invention is a nucleic acid encoding a pesticidal protein from Androctonus amoreuxi, plants comprising it, and a method of using it to increase plant pest resistance, not the protein or compositions comprising it.

4. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long. The objection is repeated for the reasons of record as set

forth in the Office action mailed 7 October 2005. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

Applicant urges that the title has been amended to recite orally active Androctonus amoreuxi proteins (response pg 10).

This is not found persuasive because the instant claims are drawn to a nucleic acid encoding a pesticidal protein from Androctonus amoreuxi, plants comprising it, and a method of using it to increase plant pest resistance, not the protein.

5. The objection to claims 7, 11 and 19 because of informalities is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

6. Claims 1-7, 13-19, 21-27, 29-31, 38, 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 7 October 2005, as applied to claims 1-7, 13-19, 21-27, 29-38, 40 and 42, due to Applicant's amendment of the claims. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

A full review of the specification indicates that nucleic acids encoding pesticidal proteins with 80% identity to SEQ ID NO:20, pesticide-encoding nucleic acids with 90% identity to bases

73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 are essential to the operation of the claimed invention.

The claims are drawn to nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20, pesticide-encoding nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, nucleic acids encoding proteins of any function comprising 10 contiguous amino acids of SEQ ID NO:20, nucleic acids of any function comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, or pesticide-encoding nucleic acids that are complementary to any of the above nucleic acids.

The claimed nucleic acids encode proteins with any type of substitution, insertion or deletion relative to SEQ ID NO:20.

The specification does not describe the relevant characteristics or motifs of the claimed nucleic acids, and the structure of proteins comprising 10 contiguous amino acids of SEQ ID NO:20 is only partial.

The implied function for nucleic acids encoding proteins comprising 10 contiguous amino acids of SEQ ID NO:20 or for nucleic acids comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 is that they, or the proteins they encode are pesticidal (see claim 23). The claimed function of nucleic acids encoding proteins with 90% identity to SEQ ID NO:20 and nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 is that the encoded proteins be

pesticidal. The pesticidal function is not specific; even the specification lists 4 pages of different pests (pg 50-53).

The structural features that distinguish pesticidal proteins with 90% identity to SEQ ID NO:20 from other proteins with 90% identity to SEQ ID NO:20 are not described in the specification, and the structural features that distinguish nucleic acids encoding pesticidal proteins with 890% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 from other nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14. The structural features that associate structure with activity against a specific pest are not described. The necessary and sufficient structural elements of a protein with pesticidal activity are not described.

All of the claimed nucleic acids are novel, and thus the prior art cannot provide no well-developed field of prior art to describe the full scope of claimed nucleic acids.

The only species described in the specification are bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, both of which encode SEQ ID NO:20.

Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 alone are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20, pesticide-encoding nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, nucleic acids encoding proteins of any function comprising 10 contiguous amino acids of SEQ ID NO:20, nucleic acids of any

function comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, or pesticide-encoding nucleic acids that are complementary to any of the above nucleic acids within the full scope of the claims. Because the sequences are not described, the method of using the sequences to alter a plant pest resistance is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that 90% sequence identity is a very predictable structural requirement and the knowledge and level of skill in the art would allow one of ordinary skill in the art to envision this nucleic acid (response pg 12).

This is not found persuasive because nucleic acids that have 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 and encode a pesticidal protein are not predictable. Likewise, nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20 are not predictable. The claims and specification require a functional protein be produced; the specification does not describe any functional variants of SEQ ID NO:20.

Applicant urges that the structural limitations are sufficient to distinguish the claimed nucleic acids from other materials (response pg 12-13).

This is not found persuasive because the structural features that associate structure with activity against a specific pest are not described. The necessary and sufficient structural elements of a protein with pesticidal activity are not described.

Applicant urges that the recitation that the nucleic acids encode proteins have pesticidal activity provides a functional characterization of the nucleic acids in the genus (response pg 13).

This is not found persuasive because Applicant has not described the structures that result in the claimed function.

7. Claims 1-7, 13-19, 21-27, 29-31, 38, 40 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:20, expression cassettes, host cells, viruses, plants and seeds comprising them, and methods of using them to alter plant pest resistance, does not reasonably provide enablement for nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20, pesticide-encoding nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, nucleic acids encoding 10 contiguous amino acids of SEQ ID NO:20, nucleic acids comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, or pesticide-encoding nucleic acids that are complementary to any of the above nucleic acids, expression cassettes, host cells, viruses, plants and seeds comprising them, and methods of using them to alter plant pest resistance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 7 October 2005, as applied to claims 1-7,

13-19, 21-27, 29-31, 38, 40 and 42, due to Applicant's amendment of the claims. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20, pesticide-encoding nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, nucleic acids encoding 10 contiguous amino acids of SEQ ID NO:20, nucleic acids comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, or pesticide-encoding nucleic acids that are complementary to any of the above nucleic acids. The claims are also drawn to expression cassettes, host cells, viruses, vectors, and plants comprising the nucleic acids, and methods of making the plants.

The instant specification, however, only provides guidance for isolation of proteins from arthropod venom and sequencing of the proteins (examples 1-4), southern corn rootworm and homopteran feeding assays (examples 5-6), construction of baculoviruses and expression of the proteins in insect cells (examples 7-8), construction of plant expression vectors encoding the pesticidal protein operably linked to a secretion signal sequence (examples 9-12), identification of cDNAs encoding neurotoxins from Centruroides vittatus and construction of vectors encoding them (examples 13-14); general guidance for transformation of rice, maize, soybean and assay of the plants for insect resistance (examples 15-20). SEQ ID NO:20 is Aam1 from Androctonus amoreuxi; SEQ ID NO:14 is a nucleic acid encoding it that uses rice-preferred codons and the sweet potato sporamin signal sequence, while SEQ IDNO:17 is optimized for expression in Stretomyces coelicolor and has the BAA signal peptide (paragraph spanning pg 11-12).

The instant specification fails to provide guidance for how to make nucleic acids encoding pesticidal proteins with 90% identity to SEQ ID NO:20 or pesticide-encoding nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14. The instant specification also fails to provide guidance for how to use nucleic acids encoding 10 contiguous amino acids of SEQ ID NO:20 and nucleic acids comprising 30 contiguous nucleotides of bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14. The instant specification fails to provide guidance for how to make or where to find pesticide-encoding nucleic acids that are complementary to any of the above nucleic acids

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:14 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain pesticidal activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making substitutions is not predictable. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically

reduced enzyme activity (see Table 1). All these mutated proteins, however, would have at least 95% identity to the original protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins with 80% identity to SEQ ID NO:20. Making all possible single amino acid substitutions in an 58 amino acid long protein like that of SEQ ID NO:20 would require making and analyzing 19^{58} nucleic acids; these proteins would have 98.3% identity to SEQ ID NO:20. Because nucleic acids encoding proteins with 90% identity to SEQ ID NO:20 would encode proteins with 2 amino acid substitutions, many more than 19^{58} nucleic acids would need to be made and analyzed. Nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 would encode proteins with up to 17 amino acid substitutions and having 39.6% identity to SEQ ID NO:20. Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with up to 17 amino acid substitutions that also have pesticidal activity would require undue experimentation.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that guidance for determining sequence identity is provided on pg 16-18 and 23-28; procedure for making variants is routine in the art, and assays are taught in the specification (response pg 14-15).

This is not found persuasive because the claims encompass nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 and encoding proteins with up to 17 amino acid substitutions and having 39.6% identity to SEQ ID NO:20. The specification does not teach 17 amino acid substitutions in SEQ ID NO:20.

Applicant urges that Lazar and Hill illustrate that one of skill in the art would be able to determine whether a particular amino acid change affected the biological activity of a protein; Bowie teaches that numerous studies have shown that proteins are highly plastic in tolerating amino acid changes (response pg 15).

This is not found persuasive because Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Nucleic acids with 90% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14 would encode proteins with up to 17 amino acid substitutions relative to SEQ ID NO:20; Guo teaches the unpredictability in making large numbers of amino acid substitutions.

Applicant urges that the quantity of experimentation amounts to two steps - making a nucleic acid encoding a protein with 90% identity to SEQ ID NO:20 or a nucleic acids with 90%

identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14, and assaying the encoded protein (response pg 15-16).

This is not found persuasive because the claims encompass nucleic acids encoding proteins with up to 17 amino acid substitutions relative to SEQ ID NO:20; given the unpredictability in making amino acid substitutions in proteins and given the lack of guidance in the specification for those substitutions, undue trail and error experimentation would have to be done in order to possibly find one that works.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at pg 1027:

> ... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

Applicant urges that pg 14-16 provide guidance for use of fragments as hybridization probes and PCR primers; other uses are well-known to those of skill in the art (response pg 16).

This is not found persuasive. Pg 14-16 teach that fragments encode proteins with biological activity - the specification teaches no 10 amino acid long fragments of SEQ ID NO:20 that retain pesticidal activity. The specification also does not teach how to use the hybridization probes or PCR primers.

8. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the

reasons of record as set forth in the Office action mailed 7 October 2005. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

Claim 19 is indefinite because it is not clear if the seed is transformed because it comprises the expression construct or because it was transformed with some other nucleic acid.

Applicant urges that claim 19 depends from claim 13, which is drawn to a plant comprising a stably transformed expression cassette; stable transformation means it is capable of being inherited by the progeny (response pg 17).

This is not found persuasive. Just because the caste is capable of being transformed doesn't mean it is. Claim 13 encompasses plants that have only one copy of the cassette, that are heterozygous for it. Those plants will only pass the cassette onto half their progeny. However, the progeny that do not have the cassette can be transformed by some other means. It is suggested that applicant amend the claim to indicate that the seeds comprise the expression cassette.

9. Claims 23-31 and 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The methods are ones of altering plant pest resistance. The only steps, however, are that of transforming a plant cell. The omitted steps are those involved in regenerating a plant from the plant cell. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2005. Applicant's arguments filed 5 January 2006 have been fully considered but they are not persuasive.

Applicant urges that no rational is provided for why the omitted steps are critical or essential, and it is not necessary to recite every element (response pg 17).

This is not found persuasive. The omitted steps are critical and essential because the methods are ones of altering plant pest resistance. However, no plant is produced in the method. The step(s) involved in regenerating a plant from the plant cell are missing. Alternatively, the claims could specify that the plant cell is in a plant. This is different from omitting minor details.

10. Claims 1-7, 11-31 and 38-43 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding SEQ ID NO:20. The closest prior art is that of Inceoglu et al (2001, Eur. J. Biochem. 268:5407-5413), who teach a nucleic acid that encodes a protein with 60% identity to SEQ ID NO:20, and Herrmann et al (WO200078957) who teach a nucleic acid with 61% identity to bases 73-249 or SEQ ID NO:17 or bases 64-240 of SEQ ID NO:14

11. Claims 11-12, 20, 39 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 28 and 43 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
May 23, 2006